Zibonta®
Botulinum toxin Type A

Zibonta® is a botulinum toxin type A product developed by Zistdaru Danesh Pharmaceutical Company, containing botulinum toxin type A as its active ingredient and formulated with human serum albumin and lactose as excipients. The product acts by inhibiting the release of acetylcholine at peripheral cholinergic nerve endings, resulting in localized muscle relaxation. Zibonta is supplied as a 500-unit lyophilized white powder intended for IM or SC administration, and must be reconstituted prior to administration using 0.9% NaCl solution.

Animal test for detection of toxin type:

The presence of type A, B and E (because of most human poisoning) was tested in mice using antitoxins A, B, and E. Mice were divided into five groups (6 mice each group), receiving either purified toxin, heat-inactivated toxin, or toxin mixed with each antitoxin. Symptoms of botulism appeared in all groups except those receiving boiled toxin or toxin neutralized by type A antitoxin. **This confirms the toxin produced is Type A.**

Zibonta and Hall A holotoxin (NT I50 KDa) sequences blast:

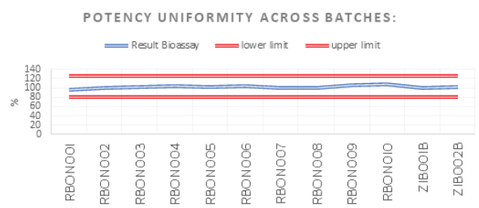
Similarity of bacterial strain that used for production of Zibonta to clostridium botulinum HAL A is **98.95%**.

Description	Scientific name	Max Score	Total Score	Query Cover	E value	Per. Ident	Acc. len	Accession
Clostridium botulinum A str Hall complete genome	Clostridium botulinum A str Hall	1194	5041	64%	0.0	98.95%	3760560	CP000727.1

Consistent Quality Across Batches

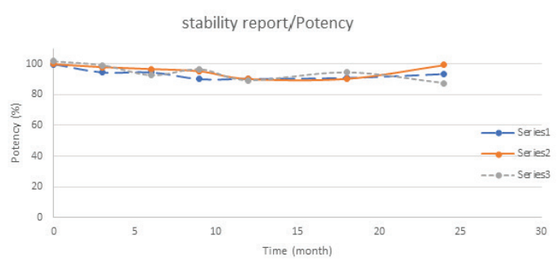
Potency test:

Data from 10 consecutive batches show potency within 90–110% of the target, as measured by mouse LD50 and cell-based assays.



Stability test:

Zibonta undergoes comprehensive stability studies using validated pharmacopoeia methods, including static light scattering and cell-based assays, to confirm retention of potency (within 90 -110% of labeled units) over 24 months.



MC/Zib/1404-05

Clinical Trials

Phase I: This study was conducted at the Center of Research and Training in Skin Diseases and Leprosy of TUMS.

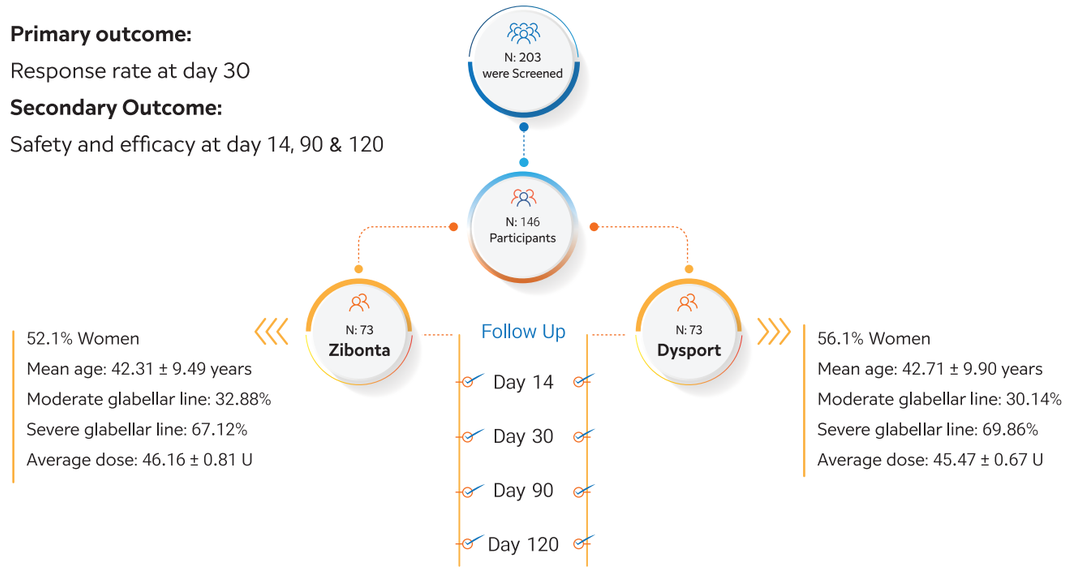
- Primary outcome: Safety
- Secondary outcome: Efficacy

A total of 5 adverse events were reported in 3 participants: 2 headache, 1 dizziness, 1 Heaviness and forehead pain, and 1 eyebrow swelling. All events resolved without requiring any medical intervention.

Results: The safety phase data showed no safety concerns related to Zibonta. All reported adverse events were **non-serious, mild or moderate, and transient**. No alarming laboratory abnormalities were observed. Overall, The data suggest that Zibonta is safe and effective for use in a Phase 3 study.

Phase III Double-Blinded, Randomized, Non-Inferiority clinical study to Evaluate Safety and Efficacy of Zibonta® in comparison with Dysport in improving the glabellar lines.

Primary outcome:
Response rate at day 30
Secondary Outcome:
Safety and efficacy at day 14, 90 & 120



Measure	Zibonta Group (n=71)	Dysport Group (n=69)	Difference (Zibonta - Dysport)
Responders (%) on Day 30	74.6%	60.9%	13.8%

Results: Zibonta® has been shown to be safe and effective in improving glabellar lines. The observed side effects were consistent with the known safety profile of the botulinum toxin.

Reconstitution

Solvent volume for reconstitution	Resulting Dose Units per 0.1 mL
1 mL	50 Units
2 mL	25 Units
2.5 mL	20 Units

Zibonta®
Botulinum toxin Type A
500 units/vial

STABLE as the Mountain's Peak

Unit 404, Official 4th Floor, North Tower-Rosemall Complex, West Hemmat Highway, Tehran, Iran
www.zistdaru.com **info@zistdaru.com** **info@zistdaru.ir**
Postal Code: 1498711712 **Tel:** +982148241000

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